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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,816	03/27/2002	Michael Valentine Agrez	SW-046 XX	9944

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,816	AGREZ ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-239* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *124-239* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed on 3/27/02, is acknowledged.

2. Claims 124-239 are pending.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically, the specification on page 55, lines 18-19, discloses RTDLDSLRTYTL, Page 68, lines 21-22, two primers, page 87 lines, 7-9, two amino acids sequences (WQTGT and RSKAK) but fail to comply with the sequence rule.

Further, the specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. Page, 13, lines 5-6, Figures 16, 20, 21, 23, 25, 28, 29, 30, 33, and 34, page 50, lines 1-2, page 55, lines 18-19, page 68, lines 21-22, page 84, lines 21-25, page 85, line 1, page 86, lines 15-16 and line 25, page 87, lines 1-2 and 7 -9, page, 88, lines 7, 9, and 25, page 89, line 13, page 91, line 17, and page 92, lines 6-9, has describe amino acids sequences that each must have a sequence identifier. Correction is required.

Applicant is reminded to amend the specification (including the Brief Description of Drawings) and claims as appropriate to reflect compliance with the Sequence Rules.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 124-128, 130-134, 138, 156-160 and 174-175, drawn to an isolated polypeptide capable of binding with a binding site of a MAP kinase of an integrin, an analog, or derivative, mutant or truncated integrin subunit β3 or a fragment thereof of an integrin subunit derived from β3 integrin subunit, and a composition thereof.

II. Claims 124-128, 130-134, 138, 156-160 and 174-175, drawn to an isolated polypeptide capable of binding with a binding site of a MAP kinase of an integrin, an analog, or derivative, mutant or truncated integrin subunit β5 or a fragment of an integrin subunit derived from β5 integrin subunit and a composition thereof.

III. Claims 124-138, 156-160 and 174-175, drawn to an isolated polypeptide capable of binding with a binding site of a MAP kinase of an integrin, an analog, or derivative or derivative, mutant or truncated integrin subunit β6 or a fragment of an integrin subunit derived from β6 integrin subunit and a composition thereof.

IV. Claims 139-142 and 176, drawn to a fusion protein incorporating an inhibitor moiety for inhibiting binding f a MAP kinase with an integrin and a composition thereof..

V. Claims 143-148, 151-155 and 177, drawn to an agent for inhibiting binding of a MAP kinase to integrin comprising a targeting moiety, inhibitor moiety, and a carrier moiety, wherein the targeting moiety is an antibody and a composition thereof.

VI. Claims 143-147, 150-155 and 177, drawn to an agent for inhibiting binding of a MAP kinase to integrin comprising a targeting moiety, inhibitor moiety, and a carrier moiety, wherein the targeting moiety is an integrin receptor targeted peptide and a composition thereof.

VII. Claims 161-162, 164-168, 170-173 and 178-180, drawn to an isolated nucleic acid sequence encoding a polypeptide, a fragment or an analog or derivative, vector, host cells and a composition thereof.

VIII. Claims 163 and 169, drawn to an isolated nucleic acid sequence encoding a fusion protein incorporating an inhibitor moiety for inhibiting binding f a MAP kinase with an integrin.

IX. Claims 181-184, drawn to an antibody specific for a binding domain of an integrin for a MAP kinase or a fragment of the integrin.

X. Claims 185-186, drawn to a method of screening for an agent capable of inhibiting binding of a MAP kinase to a binding domain of an integrin for the MAP kinase comprising test agents.

XI. Claim 187-190, drawn to a method of evaluating whether an agent is capable of inhibiting binding of a MAP kinase to a binding domain of an integrin for the MAP kinase wherein the MAP kinase is an ERK family member.

XII. Claim 187-189, drawn to a method of evaluating whether an agent is capable of inhibiting binding of a MAP kinase to a binding domain of an integrin for the MAP kinase wherein the MAP kinase is a JNK family member.

XIII. Claims 191-192, drawn to an agent identified to be capable of binding to a binding domain of an integrin for a MAP kinase.

XIV. Claim 193-200, drawn to a method of isolating an agent from a sample utilizing a molecule immobilized on a solid support and which is capable of binding to a binding site of a MAP kinase for an integrin wherein the MAP kinase is an ERK family member.

XV. Claims 193-199, drawn to a method of isolating an agent from a sample utilizing a molecule immobilized on a solid support and which is capable of binding to a binding site of a MAP kinase for an integrin wherein the MAP kinase is a JNK family member.

XVI. Claim 201, drawn to an agent to be identified by a method of isolating an agent from a sample utilizing a molecule immobilized on a solid support and which is capable of binding to a binding site of a MAP kinase for an integrin.

XVII. Claims 202-210, drawn to a method of modulating activity of a cell expressing an integrin subunit with a cytoplasmic binding domain for a MAP kinase comprising treating the cell with antisense oligonucleotide of the binding domain of the integrin subunit, wherein the MAP kinase is an ERK family.

XVIII. Claims 202-209, drawn to a method of modulating activity of a cell expressing an integrin subunit with a cytoplasmic binding domain for a MAP kinase comprising treating the cell with antisense oligonucleotide of the binding domain of the integrin subunit, wherein the MAP kinase is a JNK family.

XIX. Claims 211-216, drawn to a method of modulating activity of a cell expressing an integrin subunit with a cytoplasmic binding domain for a MAP kinase, comprising transfecting the cell with an expression vector comprising encoded by a mutagenized or truncated binding domain for the MAP kinase, wherein the MAP kinase is an ERK family.

XX. Claims 211-214 and 216, drawn to a method of modulating activity of a cell expressing an integrin subunit with a cytoplasmic binding domain for a MAP kinase, comprising transfecting the cell with an expression vector comprising encoded by or a mutagenized or truncated binding domain for the MAP kinase, wherein the MAP kinase is a JNK family.

XXI. Claims 217-219 and 222-225, drawn to a method of modulating activity of a cell expressing an integrin having a binding domain for a MAP kinase comprising treating the cell with an agent, wherein the agent is a fragment or a polypeptide, an analog or derivative thereof.

XXII. Claims 217, 220, 223-225, and 236-238, drawn to a method of modulating activity of a cell expressing an integrin having a binding domain for a MAP kinase comprising treating the cell with an agent, wherein the agent is a fusion protein.

XXIII. Claims 217, 221, 223-225 and 236-238, drawn to a method of modulating activity of a cell expressing an integrin having a binding domain for a MAP kinase comprising treating the cell with an agent, wherein the agent is comprising a target moiety, an inhibitor moiety and a carrier.

XXIV. Claims 226-235, drawn to a method of prophylaxis or therapy of cancer using antisense nucleic acid for hybridizing with a nucleic acid encoding an integrin subunit.

XXV. Claim 239, drawn to a transgenic animal with cells containing heterologeous nucleic acid encoding an integrin subunit with a mutagenised binding domain for a MAP kinase.

5. The inventions listed as Groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group III was found to have no special technical feature that defined the contribution over the prior art of Weinacker *et al* (JBC, 269:6940-6948) (see entire document).

Weinacker *et al* teach a fragment of β6 integrin subunit lacking the transmembrane and cytoplasmic domains (see figure 1 and page 6942, 1st col., under Production of Recombinant secreted integrin αvβ6), wherein said fragment comprises SEQ ID NO:2 as recited in claims 124-130.

While the prior art teachings may be silent as to the "fragment that is capable of binding with the MAP kinase" per se; the product in the reference is the same as the claimed product. Therefore "fragment that is capable of binding with the MAP kinase" is considered inherent properties of the reference fragment specially because the fragment comprises the amino acids RSKAKWQTGTNPLYR (SEQ ID NO:2).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any one of Groups I-III, VII, XIV-XV or XXI is elected, applicant is required to elect a single specific fragment such as those recited in claim 130, **or** a single specific polypeptide that comprises the amino acid recited in claims 136 or 137 or a single specific mutagenised binding domain for a MAP kinase or a single specific truncated integrin subunit. These are distinct species because their structures and physiochemical property are different which, in turn, address different therapeutic endpoints.

B. If Group XXIV is elected, applicant is required to elect a method of prophylaxis or therapy of cancer, wherein the specific cancer (such as the one recited in claim 238). These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, and represent patentably distinct subject matter.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (571) 272-0845. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 3, 2004

Christina Chan

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